In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 20-0825V UNPUBLISHED

KIMBERLY RESER,

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: February 9, 2023

Special Processing Unit (SPU); Findings of Fact; Onset; Tetanus Diphtheria Acellular Pertussis (Tdap) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Bridget Candace McCullough, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Dorian Hurley, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On July 8, 2020, Kimberly Reser filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that she suffered a shoulder injury related to vaccine administration ("SIRVA") from a Tdap vaccine she received on May 20, 2019. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

For the reasons discussed below, I find the onset of Petitioner's shoulder injury related to vaccine administration ("SIRVA") occurred within 48 hours of vaccination.

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Relevant Procedural History

Beginning in September 2021, the parties engaged in settlement discussions, attempting to reach an agreement regarding Petitioner's claim. See ECF No. 27. On March 23, 2022, the parties reached an impasse in their discussions. ECF No. 35. Respondent filed a Rule 4(c) Report on June 1, 2022 arguing that Petitioner has not established entitlement to compensation because "the evidence in this case does not establish an onset of pain in Petitioner's left shoulder within forty-eight hours of her receipt of the Tdap vaccine on May 20, 2019." Rule 4(c) Report at 6.

On August 1, 2022, Petitioner filed a Motion for a Ruling on the Record seeking a fact ruling on the issue of onset. ECF No. 38. On September 19, 2022, Respondent filed a response to the motion ("Resp."). ECF No. 40. Therefore, the issue of onset is ripe for a fact ruling.

II. Issue

At issue is whether Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). The Federal Circuit has said that

Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). Accordingly, where medical records are clear, consistent, and complete, they should be

afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005).

The Federal Circuit recently stressed, however, that records enjoy no automatic presumption of accuracy, despite their "trustworthy" evidentiary character. *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1384 (Fed. Cir. 2021). Indeed, "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998); *see also Lowrie*, 2005 WL 6117475 at *19 ("written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent").

The Court has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

Thus, medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare not only the medical records, testimony, but also all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to

medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational). And although later oral testimony that conflicts with medical records is less reliable as a general matter, it is appropriate for a special master to credit a petitioner's lay testimony where is does not conflict with the contemporaneous records. *Kirby*, 997 F.3d at 1382-84.

IV. Finding of Fact

I make the following findings after a complete review of the record, including all medical records and affidavits, the arguments in Respondent's Rule 4(c) report, the arguments in Petitioner's Motion for Ruling on the Record, and the arguments in Respondent's response thereto. I find the following points to be particularly relevant:

- Petitioner's pre-vaccination records reveal depression, type II diabetes, hypertension, and hyperlipidemia. See Ex. 11 at 4, 25.
- Petitioner received a Tdap vaccine in her left arm at a Walmart pharmacy in Clayton, Ohio, on May 20, 2019. Ex.1 at 6.
- Petitioner recalls that the shot was not immediately painful, but "started to hurt" in the time it took for her to walk out of the pharmacy to her car. Ex. 10 at ¶3. By bedtime that day, she required pain medication, and by the next morning, her shoulder was swollen, "red, hot to touch, and very sore from the shoulder to the bicep area." Id. at ¶4.
- At the time of her vaccination, Petitioner was employed as a housekeeper for a doctor Katherine Clark, D.O. Ex. 10 at ¶5; Ex. 14 at ¶2. Because Petitioner was uninsured, Dr. Clark provided some medical care for her, such as prescribing medication for her diabetes, hypertension, and hyperlipidemia. Ex. 14 at ¶2. Petitioner's prescription records reveal medications prescribed by Dr. Clark in 2019. Ex. 12 at 12.
- Petitioner recalled asking Dr. Clark about her shoulder symptoms the morning after her vaccination. Id. She recalled Dr. Clark telling her that it would take about a week to resolve. Ex. 10 at ¶5. While Dr. Clark did not specifically recall a conversation the day of vaccination, she stated that she "was aware that [Petitioner] had a lot of shoulder pain since the vaccination." Ex. 14 at ¶3. She did recall that Petitioner had "pain and redness of her shoulder." Id.

- Petitioner recalled seeking help from Dr. Clark again a week after her vaccination. Ex. 10 at ¶6. Although the swelling and redness had resolved, Petitioner continued to have pain in her shoulder and couldn't lift her arm to wash her hair, get dressed, or reach things. Id. She reported difficulty sleeping on her left side and using Advil for pain. Id. Petitioner recalled Dr. Clark advising her to use Tylenol for pain, instead of Advil, and to rest her arm in hopes that the pain would resolve. Id. Petitioner noted that she "started to use her right arm for just about everything." Id. Dr. Clark recalled that Petitioner told her that she had "decreased using her left arm for housekeeping and childcare." Ex. 14 at ¶4.
- Petitioner recalled consulting Dr. Clark again in July 2019, two months after her vaccination. Ex. 10 at ¶7. Although Petitioner remembered Dr. Clark doing an exam in her kitchen, Dr. Clark stated that she did not "examine her shoulder for range of motion and did not take a full history." Ex. 10 at ¶7. Ex. 14 at ¶3. Both Petitioner and Dr. Clark, however, recalled that Dr. Clark advised Petitioner to seek medical care, including an MRI. Ex. 5 at ¶10; Ex. 14 at 5.
- During that summer, Petitioner recalled returning to the Walmart pharmacy and speaking to the pharmacist who had administered her vaccination. Ex. 10 at ¶8. She alleges that he wrote down her information and said he would report the incident to his manager. *Id.* After several weeks, Petitioner stated, she received a call from a woman from Walmart who asked her some questions, but then determined that she "could not prove the vaccine had caused her injury." *Id.* On September 7, 2019, a VAERS report was filed by Jafar Ahmed reporting Petitioner's "lingering pain at injection site 3 months after administration." Ex. 15 at 3. Mr. Ahmed recorded his profession as "Healthcare professional/staff" and his address as 7725 Hoke Road, Clayton, Ohio, 42315, the same address as the Walmart pharmacy. *Id*; Ex. 12 at 13.
- Petitioner explained that she did not seek the medical care or MRI suggested by Dr. Clark because she did not have insurance and did not feel she could afford the costs. Ex. 10 at ¶10. After months of pain, however, she decided to make an appointment and pay out-of-pocket. Id.
- Petitioner sought treatment from a new primary care practice on October 9, 2019 (almost five months after her vaccination), where she saw family nurse practitioner, Sara Jean Neal APRN. Ex. 2 at 9. Petitioner reported at this

time that she had received a Tdap vaccine in May, and "since then her arm has been sore." *Id.* at 10. She reported that "after it happened her arm swelled up and warm to the touch with redness." *Id.* NP Neal noted that Petitioner had no health insurance at the time of the visit. *Id.* NP Neal did not make any specific findings regarding Petitioner's shoulder or a diagnosis.

- Two weeks later, on October 25, 2019, Petitioner presented to orthopedic surgeon, Adam J. Dann, D.O. Ex. 13 at 18. Petitioner reported shoulder pain since her Tdap vaccination on May 20, 2019. *Id.* Dr. Dann diagnosed "subacromial bursitis" and referred Petitioner to physical therapy to establish a home exercise plan and instructed her to follow up with him in six weeks. *Id.* at 19.
- On October 29, 2019, Petitioner presented for an initial physical therapy evaluation. Ex. 13 at 14. She reported "receiving a Tdap injection from Walmart with immediate swelling and pain." *Id.* Petitioner reported that the thought her pain would get better with time, but that it did not. *Id.* at 15. The record notes a plan of care with long term treatment goals to be met by December 10, 2019, but also that Petitioner was "self-pay and hoping for HEP only at this visit." *Id.* at 15-16. Petitioner explained that each physical therapy treatment was \$150.00 and she could not afford to pay for additional sessions. Ex. 10 at ¶11.
- Petitioner returned to her orthopedist on December 20, 2019, reporting increased pain since her last visit. Ex. 13 at 11. Dr. Dann administered a corticosteroid injection and instructed Petitioner to follow up in another six weeks. *Id.* On April 17, 2020, Petitioner returned to Dr. Dann. Ex. 13 at 8. She reported that her shoulder symptoms were unchanged and received a second corticosteroid injection. *Id.* at 8-9.
- Petitioner continued to treat her shoulder symptoms, including scheduling a surgery in the summer of 2020. Ex. 8 at 7. However, due to an abnormal EKG, the surgery was postponed. *Id.* at 17. There are no additional records.

Respondent questions the length of time between Petitioner's vaccination and any record evidence memorializing her symptoms. Resp. at 6. In particular, the "first documentation alleging any kind of adverse reaction to the vaccine" was from more than 3.5 months after her vaccination, and that the first time petitioner sought "care for her alleged shoulder pain from a medical provider" was nearly five months after vaccination. *Id.* at 6-7.

Clearly Petitioner delayed seeking care for her alleged injury. But although it is reasonable to expect that an average claimant "might seek medical treatment sooner if in fact the person was experiencing sudden post-vaccination pain," there are a variety of credible explanations for why such treatment might be delayed. *Pitts v. Sec'y of Health & Human Servs.*, No. 18-1512V, 2020 WL 2959421, at *5 (Fed. Cl. Spec. Mstr. April 29, 2020). Therefore, delay does not *per se* preclude a finding of Table onset; rather, the context for the delay informs how much weight to give the issue.

Petitioner's case is similar to the petitioner in *Winkle v. Sec'y of Health & Human Servs.*, No. 20-0485, 2021 WL 2808993, at *4 (Fed. Cl. Spec. Mstr. June 3, 2021) (finding onset within 48 hours where petitioner sought treatment for the first time nearly five months after vaccination). Like the petitioner in *Winkle*, although there was a longer-than-average delay in seeking treatment for her shoulder pain, Ms. Reser did not seek treatment for *any* medical issue during the period between her vaccination on May 20, 2019 and her first report of shoulder pain. "Such intervening treatment evidence can in many cases either corroborate a petitioner's claim or undermine it – but it is totally absent here." *Winkle*, 2021 WL 2808993, at *4. Thus, this is not a case where records show concrete opportunities to seek care in the delay period.

In addition, Petitioner has provided a reasonable and consistent explanation for her decision to delay formal medical treatment. See, e.g., Stevens v. Sec'y of Health & Human Servs, No. 90-221, 1990 WL 608693, *3 (Fed. Cl. Spec. Mstr. 1990) (noting that clear, cogent, and consistent testimony can overcome missing or contradictory medical records). Petitioner states that she did not have health insurance at the time of her injury, a fact not just established by her sworn testimony, but corroborated both by her employer, Dr. Clark, who prescribed medications for her other chronic medical conditions, and in her medical records. Ex. 10 at ¶10, Ex. 14 at ¶2, Ex. 2 at 9 (Petitioner did not have health insurance at her October 9, 2019 visit); Ex. 13 at 15-16 (Petitioner was self-pay at physical therapy). Petitioner's affidavit testimony is consistent with her contemporaneous medical records, and Dr. Clark's affidavit, regarding the onset of her pain. The Federal Circuit has held that it is appropriate to credit the lay testimony of a petitioner when said testimony does not conflict with the medical records. Kirby, 997 F.3d at 1384.

Further, Petitioner sought what medical treatment was available to her while uninsured: she consulted with her employer, Dr. Clark, who had previously provided her with basic "free" medical care. See Ex. 14 at 2 (Dr. Clark provided "some medical care" for Petitioner at her home after she lost her health insurance.). In particular, Petitioner recalled consulting with Dr. Clark the day after her vaccination, when her arm was swollen, red and painful, and again a week later when the swelling and redness had resolved (although the pain remained). Ex. 10 at ¶4-6. Dr. Clark herself recalled the redness in Petitioner's shoulder - suggesting that Petitioner consulted her about her injury at least in the first week after vaccination. Ex. 14 at 3. Dr. Clark also recalled that

Petitioner had "ongoing shoulder pain ever since the vaccination" and that she "encouraged her to get established with a primary care provider and to consider obtaining an MRI." *Id.* at ¶4-5. Petitioner also returned to the Walmart pharmacy where she received her vaccination, reporting lingering pain since her vaccination. See Ex. 15 at 3 (VAERS report by Jafar Ahmed at the same address as the Walmart pharmacy, noting "lingering pain at injection site three months after administration.").

I also note that once Petitioner sought formal treatment, her contemporaneous medical records reveal repeated consistent reports of onset of pain at or very soon after her vaccination. See Winkle, 2021 WL 2808993, at *4 (noting that petitioner's consistent statements to treatment providers should be afforded substantial weight as they were made contemporaneously and for the purpose of obtaining medical treatment). At her first visit with NP Neal on October 9, 2019, Petitioner reported a Tdap vaccination in May, but also that "since then her arm has been sore." Ex. 2 at 9. Next, Petitioner presented to an orthopedic surgeon, Dr. Dann, where she reported a Tdap vaccination on May 20, 2019 with complaints that "the shoulder has hurt since." Ex. 3 at 18. When Petitioner presented for a physical therapy initial evaluation on October 29, 2019, she reported "immediate swelling and pain" after her May 20, 2019 Tdap vaccination. Id. at 14. The totality of the record shows that Petitioner's pain began almost immediately after her vaccination and persisted thereafter. Without exception, Petitioner attributed her pain to her vaccination.

Accordingly, I find there is preponderant evidence to establish the onset of Petitioner's pain occurred within 48 hours of vaccination.

V. Scheduling Order

The following is ORDERED: Respondent shall file, by no later than <u>Monday</u>, <u>March 13, 2023</u>, a status report indicating how he intends to proceed in this case in light of the record and this fact ruling. The status report shall indicate whether he is willing to engage in discussions regarding settlement or damages or remains opposed to negotiating at this time.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master